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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	7

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/838,382	Applicant(s) DANFORTH ET AL.	
	Examiner Ja-Na A Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *3-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 6 is acknowledged.

The restricted groups have been restated:

I. Claims 1-2 are drawn to an immunovariant strain of *Eimeria maxima*, classified in class 435, subclass 258.4.

II. Claims 3,5,7-8,and 10 are drawn to a vaccine for use in combating coccidiosis in chickens comprising a concentration of oocysts of *E. maxima*, classified in class 424, subclass 271.1.

III. Claims 4, 6, 9 and 11 are drawn to a vaccine for use in combating coccidiosis in chickens comprising a concentration of oocysts of an immunovariant strain *E. maxima* that corresponds in characteristics to the strain E. maxima-I classified in class 424, subclass 267.1.

IV. Claim 7 is drawn to vaccine further comprising immunogens related to other pathogens of poultry, classified in class 424, subclass 184.1.

V. Claims 12-13 are drawn to a method of obtaining an immunovariant strain of *E. maxima* from E. *maxima* FL strain, classified in class 530, subclass 388.6.

Inventions I and II, III or IV are related as different products. The products are distinct as claimed because they have different structures and different uses. Group I is drawn to an immunovariant strain of *E. maxima;* Group II is drawn to a vaccine comprising oocysts; while group III is drawn to a vaccine comprising oocysts of an immunovariant

strain *E. maxima* which must have characteristics that correspond to the strain *E. maxima*-I and group IV is drawn to vaccine further comprising immunogens related to other pathogens of poultry. Each group has a different effect and is capable of use without the other. For instance, the *E. maxima* strain product of Group I can be used in a method to detect *E. maxima* infection however the products of Group II, III and IV could not. While Groups II, III and IV are drawn to vaccines, Group III requires the use of oocysts from an immunovariant strain which must have characteristics that correspond to the strain *E. maxima*-I, and Group IV requires the use of immunogens related to other pathogens of poultry whereas Group II does not; thus the groups comprise different components with different characteristics, thereby resulting in different effects and being capable of separate uses. Each group has a different structure, requires different components, produces different effects and is capable of different functions as compared to the other groups. Therefore, the products of the inventions are distinct as claimed.

Inventions V and I-III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, Group V is drawn to a method of obtaining an immunovariant strain of *E. maxima* from E. *maxima* FL strain. No other the other

products are drawn to the FL strain, thus the process can be used to make another and materially different product when compared to the strains or vaccines of Groups I-III. Moreover, this method would not create an immunovariant strain of *E. maxima*-I. Therefore the inventions are distinct.

Applicants' argument that the groups are not distinct is not found persuasive because contrary to applicants arguments the inventions have been shown to be distinct in view of: different structures that require different components; the production of different effects; the capability of different functions as compared to the other groups; and a process that can be used to make another and materially different product, as recited above. Thus, the vaccine comprising the immunovariant strain has a separate and distinct use with different effects and function; therefore it is patentably distinct. Moreover, each group has been shown to be distinct, thus the restriction is maintained.

Applicants argue that there would be no serious burden on the Examiner to search for the other groups. However, because the inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-IV, restriction for examination purposes as indicated is proper. Searching for the strain does not require, for example, that protective immunity of a vaccine be determined; the challenge data to be analyzed; determination of which class of patients the vaccine can be administered to, at what doses or what the mode of administration is. Therefore applicants' argument that the search is not burdensome is not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

2. Therefore claims 1-2 are under consideration in this office action, while claims 3-13 are withdrawn from consideration.

Drawings

3. The drawings are objected to because of the reasons set forth in the attached PTOL-948. However, the corrections will not be held in abeyance, and applicant must submit proposed drawing corrections in response to the requirement in the Office action.

Specification

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

5. The specification at page 11 lines 27-28 fails to recite the deposit information with respect to the Accession number and date of deposit. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-2 are drawn to an immunovariant strain of *Eimeria maxima*, said immunovariant strain designated *E. maxima*-I and an immunovariant strain of *Eimeria maxima* that corresponds in characteristics to the strain *E. maxima*-I.

The specification lacks complete deposit information for the deposit of the strain designated *E. maxima*-I. Because it is not clear that cell lines possessing the properties of *E. maxima*-I are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the *E. maxima*-I strain, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves

this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposit has not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;

2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if the test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the *E. maxima*-I strain described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

7. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "immunovariant" in claims 1-2 is a relative term which renders the claim indefinite. The term "immunovariant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in

the art would not be reasonably apprised of the scope of the invention. Neither the claims nor the specification define immunovariant. It is unclear how little or how much variation is required for a strain to be considered an immunovariant. Therefore, the claims are indefinite.

8. The phrase "corresponds in characteristics to the strain *E. maxima*-I" in claim 2 is a relative term which renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no definition of what characteristics are required of strain in order for it to correspond to said strain. There is no definition of how much correspondence is needed for a strain to correspond. Therefore, the claim is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Barta et al. Barta et al., teach obtaining the *E. maxima* Guelph and Maryland strains which were confirmed as being *E. maxima* by microscopic examination (page 486 para. 2).

The prior art *E. maxima* Guelph and Maryland strains appear to be the same as that claimed immunovariant strains. The prior art *E. maxima* Guelph and Maryland strains appear to possess the same functional characteristics. Since the Patent Office does not have the facilities for examining and comparing applicants' *E. maxima*-I with the *E. maxima* Guelph and Maryland strains of the prior art reference, the burden is upon the applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed peptide of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Therefore, Barta et al., teach an immunovariant strain of *Eimeria maxima*, and an immunovariant strain of *Eimeria maxima* that corresponds in characteristics to the strain *E. maxima*-I as claimed by the instant application.

10. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. Martin et al., teach the analysis of immunological cross-protection of five strains of *Eimeria maxima*. The strains of *Eimeria maxima* included the GS (Guelph laboratory strain and 68 (USDA laboratory strain) along with a Maryland, North Carolina and Florida strains (page 528 para. 2). All strains were confirmed to be *Eimeria maxima* by microscopic examination and isoenzyme analysis (page 528 para. 2). The GS, 68 and North Carolina strains elicited cross-immunity in chickens. Moreover, the GS, 68 and NC strains showed immunological similarities.

Since the prior art *E. maxima* GS, 68 and North Carolina strains appear to be the same as immunovariant strains. The prior art *E. maxima* GS, 68 and North Carolina

strains appear to possess the same functional characteristics. Since the Patent Office does not have the facilities for examining and comparing applicants' designated *E. maxima*-I with the *E. maxima* GS, 68 and North Carolina strains of the prior art reference, the burden is upon the applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed peptide of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Therefore, Martin et al., teach an immunovariant strain of *Eimeria maxima*, and an immunovariant strain of *Eimeria maxima* that corresponds in characteristics to the strain *E. maxima*-I as claimed by the instant application.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
October 15, 2002

MARK NAVARRO
PRIMARY EXAMINER